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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/049,427	05/06/2002	Karl Bruce Thor	X-11072	1087
25885	7590	12/03/2003	EXAMINER	
ELI LILLY AND COMPANY PATENT DIVISION P.O. BOX 6288 INDIANAPOLIS, IN 46206-6288			TRavers, Russell S	
		ART UNIT		PAPER NUMBER
		1617		

DATE MAILED: 12/03/2003

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Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)
	10/049,427	THOR, KARL BRUCE
	Examiner Russell Travers, J.D., Ph.D	Art Unit 1617

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1) Responsive to communication(s) filed on 15 September 2002.
 2a) This action is FINAL. 2b) This action is non-final.
 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4) Claim(s) 19-28, 31, 32 and 34-55 is/are pending in the application.
 4a) Of the above claim(s) 19-25, 31-33, 43-50 and 55 is/are withdrawn from consideration.
 5) Claim(s) _____ is/are allowed.
 6) Claim(s) 26-28, 34-42 and 51-54 is/are rejected.
 7) Claim(s) _____ is/are objected to.
 8) Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9) The specification is objected to by the Examiner.
 10) The drawing(s) filed on _____ is/are: a) accepted or b) objected to by the Examiner.
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
 Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. §§ 119 and 120

12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
 a) All b) Some * c) None of:
 1. Certified copies of the priority documents have been received.
 2. Certified copies of the priority documents have been received in Application No. _____.
 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

13) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application) since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.
 a) The translation of the foreign language provisional application has been received.

14) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121 since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

Attachment(s)

1) Notice of References Cited (PTO-892)
 2) Notice of Draftsperson's Patent Drawing Review (PTO-948)
 3) Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____.
 4) Interview Summary (PTO-413) Paper No(s) _____.
 5) Notice of Informal Patent Application (PTO-152)
 6) Other:

The election filed September 16, 2003 has been received and entered into the file.

Claims 19-28, 31-32, 34-55 are presented for examination.

Applicant's election with traverse of Group III, claims 26-28, 36-42 and 51-54 in Paper No. 10 is acknowledged. The traversal is on the ground(s) that the claims presented possess unity of invention. This is not found persuasive because those presented inventions are directed to independent inventions not linked by a special technological adaptation.

The requirement is still deemed proper and is therefore made FINAL.

Claims 19-25, 31-33, 43-50 and 55, drawn to non-elected subject matter are withdrawn from consideration.

The following is a quotation of the first paragraph of 35 U.S.C. § 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

The specification is objected to under 35 U.S.C. § 112, first paragraph, as failing to adequately teach how to make and/or use the invention, and thereby failing to provide an enabling disclosure.

The instant specification fails to provide information that would allow the skilled artisan to practice the instant invention without undue experimentation. Attention is directed to *In re Wands*, 8 USPQ2d 1400 (CAFC 1988) at 1404 where the court set forth the eight factors to consider when assessing if a disclosure would have required undue experimentation. Citing *Ex parte Forman*, 230 USPQ 546 (BdApls 1986) at 547 the court recited eight factors:

- 1) the quantity of experimentation necessary,
- 2) the amount of direction or guidance provided,
- 3) the presence or absence of working examples,
- 4) the nature of the invention,
- 5) the state of the prior art,
- 6) the relative skill of those in the art
- 7) the predictability of the art, and
- 8) the breadth of the claims.

Applicant fails to set forth the criteria that defines those compounds possessing selective serotonin reuptake inhibitors (SSRI) compounds useful for practicing the invention as claimed. Additionally, Applicant fails to provide information allowing the skilled artisan to ascertain these compounds without undue experimentation. In the instant case, only a limited number of those compounds possessing selective serotonin reuptake inhibitors (SSRI) compounds useful for practicing the invention as claimed examples are set forth, thereby failing to provide sufficient working examples. It is noted that these examples are neither exhaustive, nor define the class of compounds required. The pharmaceutical art is unpredictable, requiring each embodiment to be

individually assessed for physiological activity. The instant claims read on all those compounds possessing selective serotonin reuptake inhibitors (SSRI) compounds useful for practicing the invention as claimed, necessitating an exhaustive search for the embodiments suitable to practice the claimed invention. Applicants fail to provide information sufficient to practice the claimed invention, absent undue experimentation.

Claims 26-28 are rejected under 35 U.S.C. § 112, first paragraph, for the reasons set forth in the objection to the specification.

The following is a quotation of the appropriate paragraphs of 35 U.S.C. § 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless --
(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 26-=27 are rejected under 35 U.S.C. § 102(b) as being anticipated by Lee et al.

Applicants' attention is directed to *Ex parte Novitski*, 26 USPQ2d 1389 (BOPA 1993) illustrating anticipation resulting from inherent use, absent a *haec verba* recitation for such utility. In the instant application, as in *Ex parte Novitski*, *supra*, the claims are directed to preventing a malady or disease with old and well known compounds or compositions. It is now well settled law that administering compounds inherently possessing a protective utility anticipates claims directed to such protective use. Arguments that such protective use is not set forth *haec verba* are not probative. Prior use for the same utility clearly anticipates such utility, absent limitations distancing the proffered claims from the inherent anticipated use. Attempts to distance claims from anticipated utilities with specification limitations will not be successful. At page 1391, *Ex parte Novitski*, *supra*, the Board said "We are mindful that, during the patent examination, pending claims must be interpreted as broadly as their terms reasonably allow. *In re Zletz*, 893 F.2d 319, 13 USPQ2d 1320 (Fed. Cir. 1989). As often stated by the CCPA, "we will not read into claims in pending applications limitations from the specification." *In re Winkhaus*, 52 F.2d 637, 188 USPQ 219 (CCPA 1975)." In the instant application, Applicants' failure to distance the proffered claims from the anticipated prophylactic utility, renders such claims anticipated by the prior inherent use

The following is a quotation of 35 U.S.C. § 103 which forms the basis for all obviousness rejections set forth in this Office action:

A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the

subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Subject matter developed by another person, which qualifies as prior art only under subsection (f) or (g) of section 102 of this title, shall not preclude patentability under this section where the subject matter and the claimed invention were, at the time the invention was made, owned by the same person or subject to an obligation of assignment to the same person.

Claims 26-28, 34-42 and 51-54 are rejected under 35 U.S.C. § 103 as being unpatentable over Houck, Baldwin et al, Lane and Lee et al, in view of Livni et al.

Houck, Baldwin et al, Lane and Lee et al teach the various SSRI compounds as old and well known in combination with various pharmaceutical carriers and excipients in a dosage form. These medicaments are taught as useful for treating premature ejaculation, viewed by the skilled artisan as that utility herein envisioned. Claims 28, 34-42 and 51-54, and the primary reference, differ as to:

- 1) employment of the specific SSRI medicaments herein claimed, and
- 2) administration of the medicaments in those manners envisioned.

The skilled artisan, possessing a compound for an old and well known therapeutic use possesses that compounds isomers, analogs, homologs, bioisosteres for the same use. Attention is directed to *In re Ward* 141 USPQ 227 (CCPA 1964) and *Galaxo Operations U.K. Ltd. V. Quigg* 13 USPQ2d 1628, setting forth guidelines regarding therapeutic compounds relationships. Those compounds taught as obvious over the therapeutic compound are acids, ethers, esters and all salts. In the instant case, Applicants attempt to capture that activity old and well known for that class of SSRI therapeutic compounds. Absent an illustration of unexpected benefits residing in the specific compounds herein claimed, the instant claims remain properly rejected under 35 USC 103. Attention is directed to Houck, Baldwin et al, Lane and Lee et al teach the various SSRI compounds as old and well known in combination with various pharmaceutical carriers and excipients as useful for treating premature ejaculation generally. Additionally attention is directed to Livni et al teaching the claimed dapoxetine as an old and well known compound possessing SSRI activity. Possessing these teachings the skilled artisan would have been motivated to employ any SSRI compound to treat premature ejaculation and enjoyed a reasonable expectation of therapeutic success, absent information to the contrary.

Claims 28, 38-42 and 51-54 specifically require administration of specific medicament amounts and administration regimens. Livni et al teach the pharmokinetics for those compounds herein claimed providing dosage guidance to the skilled artisan to practice the invention as herein claimed. The skilled artisan would have seen the administration of therapeutic compounds by conventional means as

residing in the skilled artisan purview. Examiner notes a compound and those therapeutic benefits residing in this compound are inseparable.

Determining the active ingredient dosage level required to effect optimal therapeutic benefit is well within the

Skilled Artisan's purview and the benefits of achieving such maximization obvious, to said skilled artisan. The claims

merely recite the obvious employment of old and well known active ingredients, carriers and excipients. Thus the

only issue presented in the instant application is the obviousness of the claimed premature ejaculation methods.

No claims are allowed.

Any inquiry concerning this communication should be directed to Russell Travers at telephone number (703) 308-4603.



**Russell Travers J.D., Ph.D.
Primary Examiner
Art Unit 1617**